



UNITED STATES PATENT AND TRADEMARK OFFICE

CL
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,821	02/19/2002	Yasuyuki Suzuki	2002-0206A	2849
513	7590	02/21/2006	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,821

Applicant(s)

SUZUKI ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 7, 20, 21, 33, 40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 7 and 20 is/are allowed.
- 6) ☐ Claim(s) 21, 33, 40 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/22/05; 4/16/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, see paper, filed 12/1/05, with respect to the rejection(s) of claim(s) under 35 USC 112, 1st paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21,33,39,40,42-46 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for instant methods comprising instant melatonin receptor agonist activity enclosed in the Examples shown in the Specification, does not reasonably provide enablement for instant methods comprising all of the instantly claimed melatonin receptor agonist. Note formula in instant claims define R3 simply comprising heterocyclic groups, and R1,R2,R3 simply comprising hydrocarbon groups. Claims provide no limitation to the heterocyclic groups in terms of size and number of and types of heteroatoms. Also claims provide no limitation of hydrocarbon group in terms of size, number of atoms, or types of hydrocarbon, i.e., cyclic, straight / branched chain, saturated / unsaturated. The number of substitution would result in thousand of melatonin receptor agonist for the instant method. It would be burdensome to determine which melatonin receptor agonist work and do not work in instant application. Therefore, it is necessary for Applicant to determine a subgenus of melatonin receptor agonist that

Art Unit: 1616

would be believable for instant method. Examiner suggests that compounds selected be closely related to instant experimental melatonin receptor agonist since Applicant provides data for melatonin receptor agonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Because the functional groups on the core structure of instant formula are many and have different sizes, polarity and electronegativity, the activity of compounds of the formula would be questionable. The predictability in this art is high since a small change in a functional feature could result in a drastic change in activity and such a change can also result in an opposite effect or activity. To one of ordinary skill in the art, it would be a big job to determine the effect of all of the claimed structural changes. Because of this large burden (determination of which compounds would render desired results), an artisan would like to point out that Applicant would be entitled to a subgenus of what is being claimed. Examiner stresses that the subgenus created should be a group of related compounds based on the structure of the melatonin receptor agonist exhibited in the Examples disclosed in the specification. Examiner stresses that the subgenus created should be a group of related compounds in terms of size, polarity and electronegativity. Size of a compound determines its ability to fit into the receptor site. Polarity and electronegativity determine binding interactions between the functionality of drug (compound) and the functionality of the drug receptor site. Both of these factors should be heavily considered in the election of a subgenus group of compounds for the instant invention.

Art Unit: 1616

Allowable Subject Matter

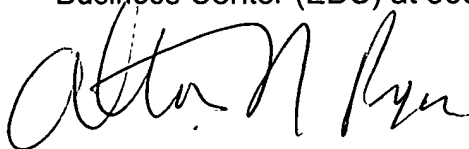
The prior art does not teach or suggest the instant composition comprising lauric diethanolamide.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alton Pryor
Primary Examiner
AU 1616